DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 5, 2015

Conmed Corporation
Ms. Anna D'Lima
Senior Specialist, Regulatory Affairs
525 French Road
Utica, New York 13502

Re: K142464
Trade/Device Name: Entriport
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: February 3, 2015
Received: February 5, 2015

Dear Ms. D'Lima:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K142464

Device Name
EntriPort Surgical Trocar System

Indications for Use *(Describe)*

The EntriPort Surgical Trocar System has applications in a variety of endoscopic procedures to provide a means of entry and access for endoscopic instruments. The Trocar may be used with or without visualization for primary and secondary insertions.

The EntriPort Mini Surgical Trocar System has applications in a variety of endoscopic procedures to provide a means of entry and access for endoscopic instruments.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K142464

510(k) Summary of Safety and Effectiveness

ConMed EntriPort Surgical Trocar System

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, ConMed Corporation is hereby submitting the 510(k) Summary of Safety and Effectiveness for 510(k) number K142464 as of February 03, 2015.

A. Submitter

ConMed Corporation
525 French Road
Utica, NY 13502

Establishment Registration: 1320894

B. Company Contact

Anna D'Lima, RAC
Senior Specialist, Regulatory Affairs
T: (315) 624-3371
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C. Device Name

Proprietary Name:	EntriPort
Common Name:	Surgical Trocar System
Classification Name:	Endoscope and accessories
Regulation Number:	876.1500
Product Code:	GCJ
Regulatory Class:	II
Panel:	General and Plastic Surgery

D. Predicate Device

Device Name:	ConMed OnePort Surgical Trocar System
Company Name:	ConMed Corporation
510(k):	K073009
Reference devices:	The follow reference devices are relevant due to their design similarities:

- ConMed's Core Audible Trocar II (K992250)
- ConMed's TroGARD Finesse Trocar System (K001597)
- Ethicon's ENDOPATH XCEL Bladeless Trocar (K032676), originally submitted as ENDOPATH III Bladeless Trocar

E. Device Description

The EntriPort Surgical Trocar System is a broad range of surgical trocars and accessories intended for use as the means for providing surgical access for various instruments during endoscopic surgery.

The EntriPort Surgical Trocar System includes both full size and mini devices, which are available in disposable (single patient use) and reposable (at least one reusable, and one disposable component) configurations. Reusable components are limited to the Reusable Cannula and accessories of the Open Entry (Hasson) Trocar.

EntriPort Surgical Trocars

Bladeless Optical Trocar

EntriPort Bladeless Optical Trocar consists of a Cannula Sleeve (Cannula, Stopcock, and Seal Body) and Bladeless Optical Obturator. The Obturator has a transparent, conical tip which accommodates an appropriately sized 0° endoscope, providing visibility of tissue layers during insertion. The Bladeless Optical Trocar is available in both disposable (single patient use), and reposable (at least one reusable, and one disposable component), configurations.

Bladed Trocar

EntriPort Bladed Trocar consists of a Cannula Sleeve (Cannula, Stopcock, and Seal Body) and a Bladed Obturator. The Bladed Obturator contains a bilateral cutting blade designed to provide a simple, linear incision that minimizes application of force to gain entry into the cavity. The Bladed Obturator is equipped with a locking, blade shield, designed to cover the blade upon entry into the cavity. The Bladed Trocar is available in both disposable (single patient use), and reposable, configurations.

Cannula Sleeve

EntriPort Cannula Sleeve (Cannula, Stopcock, and Seal Body) is a sterile, disposable (single patient use) component. When purchased separately, the Cannula Sleeve may be used in conjunction with an appropriately sized EntriPort Obturator to establish another entry port. The EntriPort Seal Body is provided attached to the Cannula and is detachable for user convenience.

Seal Body

EntriPort Seal Body seals 5mm to 12mm instruments and forms a seal when no instruments are in use. It connects to the Cannula prior to inserting either a Bladeless Optical Obturator or Bladed Obturator.

Open Entry (Hasson) Trocar

EntriPort Open Entry (Hasson) Trocar (12mm x 100mm) consists of a Cannula Sleeve (Cannula, Stopcock, and Seal Body), Open Entry (Hasson) Obturator, and Fascia Anchor Adapter (“Adapter”). It is designed to enter the cavity atraumatically, through the mini-laparotomy performed by the physician. The Adapter is attached to the Cannula and equipped with suture slots for site stabilization. The Open Entry (Hasson) Trocar is available in both disposable (single patient use), and reposable, configurations.

Reposable Trocar

EntriPort Reposable Trocar is comprised of the following disposable components: Seal Body, Obturator (Bladeless Optical or Bladed), and Stopcock. The Reposable Trocar is used with the 303 Stainless Steel, Reusable Cannula.

EntriPort Mini Surgical Trocars

Bladeless Mini Trocar

EntriPort Bladeless Mini Trocar (5 mm) consists of a Mini Cannula Sleeve (Cannula, Mini Seal Cap, and optional Stopcock) and a Bladeless Mini Obturator, available in lengths of 70 mm and 100 mm. It features a conical blunt tipped obturator to gain entry through the abdominal wall. The Bladeless Mini Trocar is available in both disposable (single patient use), and reposable (at least one reusable, and one disposable component), configurations.

Bladed Mini Trocar

EntriPort Bladed Mini Trocar (5 mm) consists of a Mini Cannula Sleeve (Cannula, Mini Seal Cap, and optional Stopcock) and a Bladed Mini Obturator, available in lengths of 70 mm and 100 mm. The obturator features a spring-loaded plastic shield that retracts as the trocar is pushed through the abdominal tissue. The shield springs forward once the obturator enters the abdominal cavity. When the tip is located in the insufflated abdomen, CO2 gas is able to escape through the open port of the obturator handle. The Bladed Mini Trocar is available in both disposable (single patient use), and reposable, configurations.

Mini Cannula Sleeve

EntriPort Mini Cannula Sleeve (Mini Cannula, Mini Seal Cap, and optional Stopcock) is a sterile, disposable (single patient use) component. When purchased separately, the Mini Cannula Sleeve may be used in conjunction with an appropriately sized EntriPort Mini Obturator to establish another entry port. The EntriPort Mini Seal Cap is provided attached to the Cannula and is detachable for user convenience.

Mini Seal Cap

The Mini Seal Cap will seal 5mm instruments and will form a seal when no instruments are in use. It connects to the Mini Cannula prior to inserting either a Bladeless Mini Obturator or Bladed Mini Obturator.

Reposable Mini Trocar

EntriPort Reposable Mini Trocar is comprised of the following disposable (single patient use) components: Mini Seal Cap, Mini Obturator (Bladeless or Bladed), and Stopcock. The reposable trocar is used with the 303 Stainless Steel, Reusable Mini Cannula. The Reusable Mini Cannula are available with, or without a stopcock port.

F. Intended Use

The EntriPort Surgical Trocar System is a broad range of surgical trocars and accessories intended for use as the means for providing surgical access for various instruments during endoscopic surgery.

G. Indications for Use

EntriPort Surgical Trocar System

The EntriPort Surgical Trocar System has applications in a variety of endoscopic procedures to provide a means of entry and access for endoscopic instruments. The Trocar may be used with or without visualization for primary and secondary insertions.

EntriPort Mini Surgical Trocar System

The EntriPort Mini Surgical Trocar System has applications in a variety of endoscopic procedures to provide a means of entry and access for endoscopic instruments.

H. Non-clinical Performance Testing

Non-clinical bench and simulated use testing demonstrated the EntriPort Surgical Trocar System is substantially equivalent to the predicate with regard to intended use, materials, technology, and performance. Product performance testing demonstrates devices comply with design specifications and applicable sections of ISO 11607-1:2006, ISO 11135-1:2007, AAMI/ANSI ST67:2011, AAMI/ANSI ST81:2004(R)2010, ISO 10993-7:2008, ISO 14971:2007, ISO 594/1:1986, and ISO 594-2:1998. Material analysis demonstrates the patient contacting materials of the EntriPort Surgical Trocar System comply with the requirements of ANSI/AAMI/ISO 10993-1:2009(R)2013. Performance testing, including blade insertion forces, entry wound defect size, instrument insertion and removal, maintenance of pneumoperitoneum, and trocar insufflation rate, demonstrates the device performance is substantially equivalent to the predicate devices.

I. Substantial Equivalence

Indications for Use

EntriPort Surgical Trocar System

The difference between the indications for use statements of the EntriPort Surgical Trocar System and the identified predicate includes removal of the term “abdominal” as it limited the application of the trocar devices. This determination is based on trocars being used for a variety of endoscopic surgical procedures, as deemed appropriate by the overseeing surgeon. There is no change to the intended use of the surgical trocar system in comparison to the predicate device. Additionally, optional use of visualization for primary and secondary trocar insertions does not alter the intended use. Product performance and user acceptance testing demonstrate the safe and effective application of the EntriPort Surgical Trocar System for its indications for use.

The differences are not critical to the intended use of the device and therefore do not affect the safety and effectiveness of the device when used as labeled.

EntriPort Mini Surgical Trocar System

As listed above for the EntriPort Surgical Trocar System, the term “abdominal” was removed. Product performance and user acceptance testing demonstrate the safe and effective application of the EntriPort Mini Surgical Trocar System for its indications for use. The difference is not critical to the intended use of the device and

therefore does not affect the safety and effectiveness of the device when used as labeled.

Technological Characteristics

The new/different technological characteristics presented by the EntriPort Surgical Trocar System (subject of this submission) are limited to design features considered to be “customer preference” driven, including the new indication of optional visualization for primary and secondary trocar insertions. The EntriPort Surgical Trocar System is identical to the predicate in that it is made up of the same operational components such as obturators (bladeless and bladed), cannula, seals, and optional insufflation ports. Both the subject and predicate systems include disposable and reposable configurations. Materials include various polymers, stainless steel, and silicone rubber. To accommodate the visualization feature of the new design, composition of some materials were updated to allow for optical transmittance. All patient contacting materials are biocompatible per ANSI/AAMI/ISO 10993-1:2009(R)2013. Product performance and user acceptance testing demonstrate the safe and effective application of the new design features for the same intended use as the predicate device.

J. Conclusion

The differences between the predicate and the modified design do not raise any new risks of safety or efficacy. Supporting information per this premarket submission confirms that the EntriPort Surgical Trocar System is safe and effective for its intended use and is substantially equivalent to the predicate devices.